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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/283,318	03/31/1999	JACK V. SMITH		9827

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JACK V SMITH
P. O. BOX 156
ARDEN, NC 28704

EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/283,318	SMITH, JACK V.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/6/2, 2/15/2, 12/4/2* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-32* is/are pending in the application.

4a) Of the above claim(s) *19-22 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group II, claims 23-29 in Paper No. 21 is acknowledged.

Claims 19-22 and 30-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 21.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 27 require that the test strip comprises an HIV-enzyme conjugated antigen as well as an indicator substrate to detect the presence of HIV antibodies. The claims are confusing as to how this method is accomplished with the enzyme as well as the indicator substance present on the same strip because a reaction between these two components will yield a positive result whether or not HIV antibody is present in the sample. This rejection also affects claims 24-26, 28 and 29.

Regarding claims 23, 24 and 27, the word "means" is preceded by the word(s) "dry chemistry test strip" in an attempt to use a "means" clause to recite a claim element as a means

for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). This rejection also affects claims 25, 26, 28 and 29.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 23 and 27 recite, "without the use of Western Blot, and Thin Layer Liquid Phase methods". These negative limitations cannot be found in the original disclosure. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). This rejection also affects claims 24-26, 28 and 29.

In paper no. 21, applicant suggests the claim language, "consisting essentially of" as a possible remedy to obviate the anticipated new matter rejection.

Applicant's proposal has been considered, but would not obviate the rejection, as there is no teaching in the disclosure for what steps or ingredients would necessarily affect the basic and

novel characteristics of the invention. Therefore, the proposed claim language would require further consideration under 35 USC 112.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstein et al. (US 5,695,930).

The claims are drawn to a method of detecting HIV antibodies on a dry chemistry strip, which is prepared by successively adding 1) a buffer and enzyme-conjugated HIV antigen and 2) an indicator substrate complex, drying the test strip, adding the strip to a sample and determining the quantity of HIV antibodies in a sample by comparing the relative intensity of the signal to a standard color chart.

Weinstein et al. (US 5,695,930) teach a method of detecting HIV antibodies with a nitrocellulose test strip that comprises an immobilized HIV antigen, p17, and a buffer and allowed to dry. The test strip method of Weinstein et al. also comprises enzymes and indicator substrates to detect a fluoroflore/enzymatic reaction. After the strip is dried, it is added to samples and are compared with standard control color intensities. See column 3, line 60-column 4, lines 2 and 64-column 5, line 42, column 7, lines 8-14, column 9, line 23-column 10, line 67 and claims 1-14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al as applied to claims 23-26 above, and further in view of Schlederer et al. (US 5,736,320).

Claims 27-29 are drawn to the same method above, except that the enzyme conjugated to the HIV antigen is horse-radish peroxidase (HRP) and the indicator substrate is tetramethylbenzidine and urea peroxide.

See the teachings of Weinstein et al. above. The reference does not teach or suggest the instant enzyme or indicator substrate to detect HIV.

However, Schlederer et al. (US 5,736,320) teach a method of detecting HRP enzyme-conjugated antigen with tetramethylbenzidine and peroxide reagent, see column 8, lines 44-67. The HRP enzyme can be conjugated to an HIV antigen to detect the presence of an HIV antibody in a sample, see claims 1-5, 9, 12, 15, 16, 20-25, 29, 31, 32, 35, 36 and 40. One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the enzyme/substrate of Weinstein et al. to detect the presence of HIV antibodies on a dry test means because they are conventionally used in the assay art to easily detect substances within an aqueous sample, taught by Schlederer et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for substituting the enzyme/substrate indicator of Schlederer et al. with the enzyme/indicator of Weinstein et al.

because both methods are drawn to detecting HIV antigens by chemical luminescence or fluorescence. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
February 24, 2003

JEFFREY STUCKER
PRIMARY EXAMINER